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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,480	03/29/2004	Nicholas M. Valiante JR.	20426.003	9427

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/814,480	VALIANTE, NICHOLAS M.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,24,26,30 and 36-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 24, 26, 30, 36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 1/16/2007. Claim(s) 1-20, 22-23, 25, 27-29, 31-35 have been cancelled. Claim(s) 21, 24, 26, 30, 36-39 are pending. Claim(s) 21, 24, 30, 39 have been amended. Claim(s) 21, 24, 26, 30, 36-39 are examined herein.

Applicant's amendments have rendered the 103(a) rejection of the last Office Action moot, therefore hereby withdrawn. The following new rejections will now apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 21, 24, 26, 36-39 is/are rejected under 35 U.S.C. 103(a) as being obvious over Das et al. (US Patent 6,596,746 B1) in view of Klaviniskis et al. (US Application 2003/014792 A1) and Ryan (US Patent 4,171,353).

The instant claims are directed to a composition comprising a SMIP compound of formula XXI and an antigen in an oil-in-water emulsion.

Das et al. teach novel cyclic compounds and their use in the treatment of immunologic and oncologic disorders (abstract). A preferred compound is N-(2-chloro-6-methylphenyl)-2-{{2-(4-morpholinylmethyl)-1H-benzimidazole-5-yl}amino]-5-thiazolecarboxamide (col. 297, lines 18-20). Some examples of disorders that can be treated include respiratory allergies, such as asthma (col. 24, line 1), and colon (col. 23, line 64), breast, and lung cancer (col. 24, lines 62-64). Das et al. also teach that other therapeutic agents may be administered with the compounds of the instant invention (col. 23, lines 34-37), such as other anti-cancer agents, biological response modifiers, immune modulators, and monoclonal antibodies (col. 27, lines 63-66).

A novel useful compound that is isomeric with the prior art compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. *In re Norris*, 179 F.2d. 970, 84 USPQ 458 (CCPA 1970). Compounds, which differ only in the placement of substituents in a ring system, are obvious absent unexpected results. *In re Jones*, 162 F.2d 638, 74 USPQ 152 (CCPA 1947).

However, Das et al. fail to disclose specifically an antigen in the oil-in-water emulsion.

Klaviniskis et al. disclose a composition comprising spores of Bacillus subtilis as a method of stimulating immune responsiveness in a subject. The spores have an adjuvant, immunomodulatory, immune potentiation effect in a subject (abstract). Klaviniskis et al. also disclose that antigens can be used as adjuvant in the present composition (pg. 15, section 0155) to boost an immune response in a mammal (abstract). In addition to the MF59 adjuvant (pg. 2, section 0014), other antigens that are mentioned to be useful are influenza, hemagglutinin, and neuraminidase (pg. 14, section 0147). Furthermore, Klaviniskis et al. disclose that the present composition can be used to treat allergic asthma and lung, breast, and colon cancers (pg. 7, section 0082-0083).

Ryan teach that immunological adjuvants most commonly used to enhance immune responses in animals including man are generally divided into two types, one being oil-in-water emulsion type adjuvant. The oil-in-water emulsion type adjuvants provide a slow release of the antigen by virtue of its emulsified state in the oil (col. 1, lines 26-39).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to combine the antigens as taught by Klaviniskis et al. with the composition as taught by Das et al. to form an oil-in-water emulsion.

A person of ordinary skill in the art would have been motivated to make this combination because (1) both Das and Klaviniskis et al. disclose a method of treating immunologic disorders, such as asthma, as well as breast, lung, and colon cancers; (2)

Das et al. teaches the use of other therapeutic agents in the composition, such as other anti-cancer agents, biological response modifiers, immune modulators, and monoclonal antibodies; (3) Klaviniskis et al. disclose a composition comprising spores, which contain adjuvants that have an immunomodulatory effect and stimulates immune responsiveness; and (4) oil-in-water emulsion are well-known immunological adjuvants that provide slow release of the antigen. Therefore, one of ordinary skill in the art would have had a reasonable expectancy to successfully make a composition comprising the active agent disclosed by Das and the antigen and adjuvant disclosed by Klaviniskis, that would effectively treat immunologic disorders, such as asthma, as well as breast, lung, and colon cancers by stimulating the immune system and enhancing an immune response, while providing slow release of the antigen.

Examiner respectfully points out that the intended use of claim 26, directed to the biological function of the composition is given no patentable weight.

It is well known in Patent Law that if applicants are claiming a biological pathway as the basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated, and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompasses by the claims.

Claim Objections

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant argues that there is no motivation or reasonable expectation of success to combine the Das and Klaviniskis references since they oppose each other in terms of the whether the T cells are blocked or activated.

This is not persuasive because while the mechanism of action is relevant, the fact remains that both Das and Klaviniskis et al. clearly disclose a method of treating immunologic disorders, such as asthma, as well as breast, lung, and colon cancers. Furthermore, Das et al. teaches the use of other therapeutic agents in the composition, such as other anti-cancer agents, biological response modifiers, immune modulators, and monoclonal antibodies, which Klaviniskis provides in the form of antigens and adjuvants.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

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